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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,031	07/23/2001	David Cook	Cerus-4900.10	4750

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EXAMINER
PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,031	COOK ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-20 are presented for examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 1, 2002, has been received. The submission is in compliance with the provisions of 37 CFR 1.97. However, because the parent application is not accessible at this time, the information disclosure statement cannot be considered at this time. Once access to the parent application is obtained, the IDS will be considered in full.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of

this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 2, 4-8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Platz et al (U.S. Pat. 5,418,130).

Platz discloses processes wherein blood products, including red blood cells, are treated with quaternary ammonium or phosphonium-substituted halogenated psoralens to remove pathogens. See abstract. Note specifically that these compounds are cationic and, to the extent they can be derived from furocoumarin, can be considered "furocoumarin derivatives", as recited in claim 7. Note further Platz's preferred use of compounds containing ester moieties in the linker portion of the compounds (columns 10 and 11), thereby meeting the limitation requiring a frangible linker moiety. Platz further discloses that glutathione is suitable for use as a quencher to augment red cell defenses against free radical initiated damage. See col. 26, lines 41-44. The reference therefore discloses processes having all of the steps recited in the cited claims. Thus, Platz anticipates the cited claims.

Claims 1-12, 14, 15 and 18-20 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Cook et al (U.S. Pat. 6,093,725) ("Cook '725").

Cook '725 discloses inactivating pathogens in red blood cell preparations using the claimed compound, β-alanine, N-(acridin-9-yl,2-[bis(2-chloroethyl)amino]ethyl ester (see Example 9, at columns 34 and 35, see also column 23), and also discloses the use of glutathione as a quencher (see column 22). A holding of anticipation over the cited claims is therefore required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al (U.S. Pat. 5,418,130).

As discussed above, Platz discloses a process wherein a pathogen-inactivating compound having the claimed structure, including frangible linker moiety, is quenched using glutathione. Platz does not disclose specific process parameters for the quenching process. However, the artisan of ordinary skill, seeking to practice Platz's inactivation process, clearly would have considered the determination of suitable and/or optimum process parameters, such as concentration of inactivating and quenching compounds, as well as duration of inactivation and quenching treatments, to have been a routine matter of optimization, and therefore obvious to the artisan of ordinary skill. A holding of obviousness over the cited claims is therefore required.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al (U.S. Pat. 6,093,725).

As discussed above, Cook '725 discloses inactivating pathogens in red blood cell preparations using the claimed compound, β-alanine, N-(acridin-9-yl,2-[bis(2-

chloroethyl)amino]ethyl ester, and also discloses the use of glutathione as a quencher. Cook '725 does not disclose specific process parameters for the quenching process. However, the artisan of ordinary skill, seeking to practice Cook '725's inactivation process, clearly would have considered the determination of suitable and/or optimum process parameters, such as concentration of inactivating and quenching compounds, as well as duration of inactivation and quenching treatments, to have been a routine matter of optimization, and therefore obvious to the artisan of ordinary skill. A holding of obviousness over the cited claims is therefore required.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-117 of U.S. Patent No. 6,270,952 B1 ("Cook '952"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims entirely encompass embodiments recited within the patented claims. Note specifically that in addition to the quenching steps recited in claim 1 of Cook '952, claim 8 of Cook '952 recites the presence of a frangible linker, claim 10 of Cook '952 recites the use of the same pathogen inactivating compound recited in instant claim 18, and claim 14 of Cook '952 recites glutathione as the quencher. A terminal disclaimer is clearly required.

2. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-35 of U.S. Patent No. 6,093,725 ("Cook '725) in view of Platz et al (U.S. Pat. 5,418,130).

Claims 20-35 of Cook '725 recite inactivation of pathogens in materials, including the blood cell compositions recited in the instant claims, using the same compounds as recited in the instant claims. Claims 20-35 of Cook '725 differ from the instant claims in that they do not disclose a step of quenching

the pathogen-inactivating reaction. However, as discussed above, Platz discloses that glutathione is suitable for use as a quencher to augment red cell defenses against free radical initiated damage. *See* col. 26, lines 41-44. Thus, the artisan of ordinary skill, recognizing the advantage of adding a quencher such as glutathione to protect the red cells from free radical damage caused by the pathogen inactivating compound of the patented claims, would have been motivated to have added a quenching to the pathogen inactivating process recited in claims 20-35 of Cook '725. Thus, because the instant claims do not patentably differ from the claims of Cook '725 when taken in view of Platz, a terminal disclaimer is clearly required.

As discussed immediately above, claims 1-20 are directed to an invention not patentably distinct from claims 20-35 of commonly assigned U.S. Pat. 6,093,725. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Pat. 6,093,725, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at

the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
September 13, 2002